SEP 21 2000

K002004

Zymed

Zymed Inc.
1201-B N. Rice Ave.
Oxnard, California 93030
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510(k) Summary

Submitter:

Gretel Lumley, Quality Assurance Engineer
Zymed Medical Instrumentation
1201 B North Rice Avenue
Fax: 805-604-0493
Phone: 800-235-5941 (417)
Date of Summary: 6-29-00
Contact: G. Lumley – see above

Trade Name: Zybit
Common Name: ECG Transmission System
Classification Name: Telephone electrocardiograph transmitter and receiver – (per 21 CFR 870.2920)

Legally marketed device to which S.E. is claimed.
Zymed Holter Scanner Model Holter 2000 – 510(k) K990170
PaceArt HomeTrak Plus EASI Event Recorder System – 510(k) K982090

Description: Zybit is an accessory to Zymed's Holter Scanner Model Holter 2000 that sends recorded cardiac ECG data from a remote site to a central site equipped with Zymed's Holter Scanner Model Holter 2000 for analysis. Zymed's Holter Scanner Model Holter 2000 software analyzes the ECG and provides reports on a variety of cardiac data. The cardiac data that is analyzed is individual ECG waveforms and patterns of consecutive waveforms. The analysis is then returned to the remote site. Cardiac data provided by Zymed's Holter Scanner Model Holter 2000 and transmitted by Zybit is used by trained medical personnel to diagnosis patients with various cardiac rhythm patterns.

Zybit is an accessory that provides a means to transmit data to and from Zymed's Holter Scanner Model Holter 2000. Data can be transferred via modem, ISDN lines, T1 lines, Internet or Intranet. All transferred date is encrypted and can only be accessed through password control by the remote and central sites. Zybit software has data checks to prevent the loss or corruption of data during transmission. Additionally, Zybit will resend data when a transmission is interrupted.

Indications for Use:

1. Telephonic transmission of recorded ECG from a remote site to central station for analysis and telephonic transmission of the analysis back to the remote site.

Review of Technology characteristics compared to the predicate device:

Platform	Holter Scanner Model Holter 2000 (Old) *Holter*	Holter Scanner Model Holter 2000 with Zybit Software (New) *Holter*
Type	IBM PC AT Compatible	Same
CPU	266 MHz Pentium II or greater	Same
RAM	128 Mbytes or greater	Same
Hard Disk	6 Gbytes or greater	Same
Floppy Disk	1.44 Mbytes	Same
Display	SVGA, 1024 x 768 pixels	Same
Touch Screen	No	Same
Mouse	Yes	Same
Data Acquisition		
Number of Channels	2 or 3	Same
Resolution	8 – 16 bit	Same
Sampling Frequency	75 - 200 samples per second	Same
Playback Speed	Up to 800 times real time	Same
Digital Input	Yes	Same
Network Card	**No**	**Yes**
Telephonic Input	**No**	**Yes**
Software		
Operating System	Windows 98 & Windows NT	Same
Hardware and Software Diagnostics	Included	Same

Specification/Feature	Current Transmission System HomeTrak Plus EASI Event Recorder Sytem	New Transmission System Zybit Remote Site	
Type	IBM PC AT Compatible	Same	Hardware Supplied By User
CPU	166 Mhz Pentium or greater	266 Mhz Pentium II or greater	
RAM	2 M Bytes Minimum	64 M Bytes Minimum	
Hard Disk	2.1 G Bytes Minimum	6 Gbytes Minimum	
Display	SVGA	Same	
Modem	**28.8 K with dedicated line**	**56.6 K with dedicated line**	
Internet	**No**	**Yes**	
ISDN Line	**No**	**Yes**	
T1 Line	**No**	**Yes**	

Specification/Feature	Current Transmission System HomeTrak Plus EASI Event Recorder Sytem	New Transmission System Zybit Central Site
Type	IBM PC AT Compatible	Same
CPU	166 Mhz Pentium or greater	266 Mhz Pentium II or greater
RAM	32 M Bytes Minimum	64 M Bytes Minimum
Hard Disk	2.1 G Bytes Minimum	6 Gbytes Minimum
Display	SVGA	Same
Modem	**28.8 K with dedicated line**	**56.6 K with dedicated line**
Internet	**No**	**Yes**
ISDN Line	**No**	**Yes**
T1 Line	**No**	**Yes**
Network Card	**No**	**Yes**

Hardware Supplied By User

The only difference between the two Zymed systems is the use of telephonic data input. The only difference between the Zymed and the Pace Art transmission systems is that the Zymed system will transmit data using Internet, ISDN Lines, T1 Lines and Modem whereas the Pace Art system only transmits data using a modem.

In summary, performance data between the two systems were nearly identical, and therefore, supports a claim of Substantial Equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 21 2000

Ms. Gretel Lumley
Quality Assurance Engineer
Zymed Medical Instruments
1201-B N Rice Ave.
Oxnard, CA 93030

Re: K002004
Trade Name: ZYBIT
Regulatory Class: II (two)
Product Code: DXH
Dated: June 29, 2000
Received: July 3, 2000

Dear Ms. Lumley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K002004

Device Name: Zybit

Indications for Use:

- Telephonic transmission of recorded ECG from a remote site to central station for analysis and telephonic transmission of the analysis back to the remote site.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for

Division of [illegible] & Respiratory Devices
510(k) Number K002004

Prescription Use ____ or Over-The-Counter Use ____
(CFR21 CFR 801.109)